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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/068,663	02/06/2002	Chuan Li		9010

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EXAMINER	
WALLENHORST, MAUREEN	
ART UNIT	PAPER NUMBER
1743	

DATE MAILED: 07/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/068,663	LI, CHUAN	
	Examiner	Art Unit	
	Maureen M. Wallenhorst	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 June 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10 and 12-20* is/are rejected.

7)☒ Claim(s) *11* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *6/24/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. Claim 11 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot reference two different claims for different features. See MPEP § 608.01(n). Accordingly, the claim has not been further treated on the merits.

2. Claims 6, 10, and 12-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

On lines 2-3 of claim 6, the phrase "where first container means" is indefinite since a first container is not positively recited previously in claim 6. This phrase should be changed to –where the at least one container means--.

On line 5 of claim 10, the phrase "combining the polypeptides that each has different" does not make proper sense. This phrase should be changed to –combining the polypeptides such that each has different--.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 1-10 and 12-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Novagen catalog (submitted in the Information Disclosure Statement submitted on June 24, 2003) in view of both Hartley (US Patent no. 5,834,201, also submitted in the IDS filed June 24, 2003) and the New England BioLabs catalog (also submitted in the IDS filed June 24, 2003).

The Novagen catalog teaches of a set of Perfect Protein™ Markers and a method for making. The set comprises multiple recombinant proteins, each having a defined size such as 15, 25, 35, 50, 75, 100 and 150 kDa. The proteins are designed for use in SDS-polyacrylamide gel electrophoresis, and enable a highly accurate size determination of unknown samples. The multiple proteins are also all present in a known mass or amount that enables estimation of the concentration of sample proteins using a detection assay based upon staining with Coomassie blue. The Novagen catalog teaches that each vial of different size protein in the set contains either 50 micrograms of protein per band or 100 micrograms of protein per band for a 2X reference. See page 239 in the Novagen catalog. Therefore, the protein marker set taught by the Novagen catalog contains multiple proteins, each having a different size from one another and each being at either one of two different amounts or concentrations. The Novagen catalog fails to teach that each of the different size proteins in the set is present at a different amount from any of the other proteins.

Hartley (US Patent no. 5,834,201) and the New England BioLabs catalog each teach of nucleic acid marker ladders that comprise a collection of different size nucleic acid fragments resulting from the digestion of one or more nucleic acids by a restriction endonuclease. Hartley teaches that the different size nucleic acids in the ladder are useful as a standard to be used during electrophoresis in order to determine the size of unknown nucleic acid fragments. Hartley

also teaches that the marker ladder not only allows one to size an unknown nucleic acid but also to determine the mass or amount of an unknown nucleic acid since each of the nucleic acid fragments in the ladder are present at a known different molecular mass or amount. The molecular mass or amount of an unknown nucleic acid can be determined following agarose gel electrophoresis and ethidium bromide staining by comparing the intensity of the fluorescence of a fragment of unknown molecular mass or amount with the intensity of a similarly sized fragment of known molecular mass or amount. See lines 58-67 in column 2, lines 1-12 in column 3 and lines 31-46 in column 5 of Hartley. See page 123 in the New England BioLabs catalog that describes a DNA ladder having multiple DNA fragments therein, each at a different size (i.e. different number of base pairs) and at a different amount (i.e. DNA mass) from one another.

Based upon the combination of the Novagen catalog with both Hartley and the New England BioLabs catalog, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to provide each of the different size proteins in the set taught by the Novagen catalog at a different amount from any of the other proteins since the Novagen catalog does teach to provide at least two of the different size proteins at different concentrations so as to provide a reference sample, and since both Hartley and the New England BioLabs catalog teach that it is advantageous to provide different size nucleic acid fragments in a marker ladder at different concentrations from one another in order to be able to estimate both the size and amounts of unknown nucleic acid fragments. One of ordinary skill in the art would have found it obvious to extend the teachings disclosed by Hartley and the New England BioLabs catalog concerning nucleic acid marker ladders to the protein marker ladder taught by the Novagen

catalog since a protein marker ladder is made by nucleic acid fragments that encode for one or more of the polypeptides of different size in the ladder.

6. Claims 1-10 and 12-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hartley (US Patent no. 5,449,758, submitted in the IDS filed on June 24, 2003) in view of both Hartley (US Patent no. 5,834,201, also submitted in the IDS filed June 24, 2003) and the New England BioLabs catalog (also submitted in the IDS filed June 24, 2003). For a teaching of Hartley ('201) and the New England BioLabs catalog, see previous paragraphs in this Office action.

Hartley ('758) teaches of a protein size marker ladder that comprises at least three polypeptide fragments of different size. Hartley also teaches of the nucleic acid fragments that encode for the different size polypeptides. Hartley teaches that the different size polypeptides can be present in a kit comprising a carrier means having in close confinement therein at least one container means holding the polypeptides of the protein ladder. Hartley also teaches of a method for using the protein ladder to estimate the size of a sample protein by electrophoresing simultaneously in separate lanes of a gel the protein ladder and the sample protein, and comparing the size of fragments of the protein ladder with the size of the sample protein. See lines 28-59 in column 1 of Hartley ('758). Hartley ('758) fails to teach that each of the different size polypeptides in the ladder is present at a different amount from any of the other polypeptides.

Based upon the combination of Hartley ('758) with both Hartley ('201) and the New England BioLabs catalog, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to provide each of the different size polypeptides in the ladder

taught by Hartley ('758) at a different amount from any of the other polypeptides since both Hartley ('201) and the New England BioLabs catalog teach that it is advantageous to provide different size nucleic acid fragments in a marker ladder at different concentrations from one another in order to be able to estimate both the size and amounts of unknown nucleic acid fragments. One of ordinary skill in the art would have found it obvious to extend the teachings disclosed by Hartley ('201) and the New England BioLabs catalog concerning nucleic acid marker ladders to the protein marker ladder taught by Hartley ('758) since a protein marker ladder is made by nucleic acid fragments that encode for one or more of the polypeptides of different size in the ladder.

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Please make note of: Chatterjee et al who teach of a method for the production of proteins.

8. Applicant's arguments with respect to claims 1-20 have been considered but are moot in view of the new ground(s) of rejection.

The previous objection to the abstract and rejections of the claims under 35 USC 112, second paragraph made in the last Office action mailed on March 28, 2003 have been withdrawn in view of Applicant's amendments to the abstract and claims in the response received on June 24, 2003. The previous prior art rejections under 35 USC 103 made in the last Office action mailed on March 28, 2003 have been withdrawn in favor of the newly presented rejections under this statute set forth above. These new prior art rejections are based upon references submitted by Applicant in an Information Disclosure Statement filed after the mailing of the first Office

action. Where the information in an IDS is submitted after the mailing of a first Office action with no certification under 37 CFR 1.97(e), the examiner may use the information submitted and make the next Office action final whether or not the claims have been amended, provided that no other new ground of rejection which was not necessitated by amendment to the claims is introduced by the examiner. See MPEP 706.07(a). For this reason, this Office action is being made final.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen M. Wallenhorst whose telephone number is 571-272-1266. The examiner can normally be reached on Monday-Wednesday from 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maureen M. Wallenhorst
Primary Examiner
Art Unit 1743

mmw

July 25, 2005

Maureen M. Wallenhorst
MAUREEN M. WALLENHORST
PRIMARY EXAMINER
GROUP [redacted] 1700